

## **REMARKS**

The present application has been reviewed in light of the Office Action mailed December 27, 2007. By the present amendment, claims 1 and 2 have been amended to more clearly distinguish Applicant's novel invention from the cited art of record. Claims 3-8 remain in their original form.

### **New Oath and Declaration**

By this amendment, Applicant has submitted a new oath and declaration in accordance with MPEP §§602.01 and 602.02.

### **Claim Rejection – 35 USC § 103**

Claims 1-8 were rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent Application Publication No. 2004/0028502 to Cummins (hereinafter "Cummins") in view of U.S. Patent No. 5,282,829 issued to Hermes (hereinafter "Hermes").

According to § 2143.03 of the MPEP, "[t]o establish prima facie obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art." Applicant respectfully submits that Cummins either taken alone or in combination with Hermes does not teach, disclose or in any way even remotely suggests the novel

combination of elements recited in claims 1-6 of Applicant's invention (as amended). In fact, it is respectfully submitted that the combination as suggested by the Examiner would teach away from Applicant's invention (as amended).

The Examiner references the fact that the Cummins reference teaches a surgical fastener having a deformable base leg and a tissue piercing tip but does not disclose a capillary in the base leg of the fastener of the surgical fastener. The Examiner relies on the combination of the Hermes reference for teaching the base leg having "multiple rupturable capillaries defining a reservoir that retains a bonding, medicinal or therapeutic agent" (See Column 5, lines 13-61 and Column 6, lines 18-33).

With all due respect to the Examiner's incite into this area, upon careful review of this reference, Hermes does not teach a rupturable capillary but, in fact, teaches the polar opposite of such an event and in every instance teaches "diffusion", "osmotically", "rate of diffusion", "porous", "ultimately control the rate of release of the medicinal", "the medicinal diffuses or leaks from the fastener 30 to the target area" and "governed by zero order kinetics".<sup>1</sup> More particularly, Hermes teaches a slow and methodic leaking, diffusion or release of the medicinal into the target area. In fact, Hermes relies on chemical reactions, rates of diffusion, zero order kinetics and the size of pores to govern the rate at which the medicant is absorbed into the target tissue through the implant in a controlled manner.

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<sup>1</sup> A zero-order reaction has a rate which is independent of the concentration of the reactant(s). Increasing the concentration of the reacting species will not speed up the rate of the reaction.

In contrast, claims 1 and 2 as amended recite dispensing of the fluid simultaneously upon deformation of a surgical fastener (typically by firing a stapler or clip applier) which by definition tends to be a more immediate event which involves the rapid, physical buckling or bending of the fastener into a desired configuration against the skin tissue while at the same expelling the fluid from the capillary. As can be appreciated, this is clearly different than osmotically infusing medicant into tissue in a controlled manner as taught by Hermes (See Column 5, lines 42-45). Applicant's invention involves mechanically exploding medicant or bio-adhesive from a capillary simultaneously upon deformation of the fastener irrespective of the infusion rate, zero order kinetics or pore size clearly making Applicant's invention patentably distinguishable over Cummins either taken alone or in any conceivable combination with Hermes.

Moreover, no motivation exists to combine the fasteners of Cummins and Hermes since any plausible combination of this sort would depart from the very teachings of Hermes - slow, deliberate infusion of medicant into a target area at a controlled rate (e.g., See Column 5, line, 13-15, 42-45). Put simply, it is respectfully submitted that the expulsion of fluid from a capillary by deforming a fastener as taught by Applicant's invention radically departs from the teachings of Hermes, i.e., the "controlled" delivery of medicant to a target area. For at least these reasons, claims 1 and 2 are not rendered obvious by the combination of Cummins and Hermes and are believed patentably distinguishable.

Claims 3-8 depend from independent claims 1 and 2, respectively, either directly or indirectly and are also believed allowable for at least the reasons stated above with respect to claims 1 and 2, respectively.

## CONCLUSION

In view of the foregoing, it is therefore respectfully submitted that all of the claims of the application as presented, namely, claims 1-8, are patentably distinguishable over the cited references and the other references of record. Accordingly, early and favorable consideration of this application is respectfully requested. Should the Examiner believe that a telephone or personal interview may facilitate resolution of any remaining matters, she is respectfully requested to contact Applicant's attorney at the number indicated below.

Please charge any deficiency as well as any other fee(s) that may become due under 37 C.F.R. § 1.16 and/or 1.17 at any time during the pendency of this application, or credit any overpayment of such fee(s), to Deposit Account No. 21-0550.



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